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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,510	06/26/2000	JOHN P. HELGESON	WARF H108	6417

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 11/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,510

Examiner

David H Kruse

Applicant(s)

HELGESON ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Application

1. This Office Action is in response to the Amendment and Remarks filed 26 August 2002.
2. Claim 2 has been cancelled without prejudice as requested.
3. The Abstract submitted 26 August 2002 has been entered into the specification.
The outstanding objection to the specification is withdrawn.
4. The Information Disclosure Statement filed 18 September 2000 has been considered, a signed copy is attached hereto.
5. The draftsman has approved the drawings.
6. The objection to claim 9 is withdrawn in view of Applicant's amendment to said claim.
7. The outstanding rejection of claim 4 under 35 U.S.C. § 112, second paragraph, as indefinite is withdrawn in view of Applicant's correction of the dependency of said claim.
8. The rejection of claims 1, 5 and 6 under 35 U.S.C. § 102(b) as anticipated by Helgeson *et al* is withdrawn in view of the rejection put forth below under 35 U.S.C. § 102(b).
9. The rejection of claims 8 and 9 under 35 U.S.C. § 102(b) as anticipated by Barry *et al* is withdrawn in view of Applicant's amendment to claim 8.

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10. The rejection of claims 3 and 7 under 35 U.S.C. § 103(a) as obvious over Schumman *et al* in view of Thieme *et al* is withdrawn in view of Applicant's arguments (pages 9-10 of the Remarks).

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

12. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicant's attention is directed to page 11, lines 5 and 6, and page 22, line 3.

Appropriate correction is required.

Claim Objections

13. Claim 1 is objected to because of the following informalities: at line 2 the phrase "a genome" is unclear because it appears that *Solanum bulbocastanum* is a diploid plant comprising a single genome, it is suggested that the phrase -- the genome -- be used. Appropriate correction is required.

Claim Rejections - 35 USC § 112

14. Claims 3, 4, 7 and 9 are rejected and claim 8 remains rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 3, the sole designation of a marker by a non-art recognized designation is arbitrary and creates ambiguity in the claims. For example, the RAPD or RFLP

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markers disclosed in this application could be designated by some other arbitrary means, or the assignment of the marker name could be arbitrarily changed to designate another marker. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to the sequence identification number that identifies the claimed marker would obviate this rejection.

Claim 4 is indefinite because it is unclear to which marker each SEQ ID NO is directed to in the list of species at claim 3, hence it is unclear what the metes and bounds of claim 4 are.

At claim 7 is indefinite because at line 4 the phrase "the gene" is unclear as to the metes and bounds of the claimed invention. At claim 1 the potato plant comprises a segment of chromosome 8 of a genome from *Solanum bulbocastanum* which comprises "the gene", hence it is unclear if the plant transforming vector comprises a segment of chromosome 8 of a genome from *Solanum bulbocastanum* or if said vector only comprises that portion of chromosome 8 of a genome from *Solanum bulbocastanum* which is a gene that confers resistance to late blight.

Claim 8 remains indefinite as being generally narrative, and remains unclear. It is suggested that the claim be amended to read -- An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 5, or a nucleotide sequence complementary thereto. --. This rejection is repeated for the reason of record in the previous Office action mailed 22 April 2002. Applicant does not specifically argue the

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rejection in the response filed 26 August 2002, on pages 7-8. The Examiner has suggested claim language that would obviate the instant rejection.

Claim 9 is indefinite because it depends upon claim 8 and does not obviate the indefiniteness in claim 8.

15. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 1 and 3-7 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a late blight-resistant potato plant comprising a segment of chromosome 8 of a genome from *Solanum bulbocastanum* which comprises a gene that confers said resistance to late blight, said resistance gene is incorporated into the plant by somatic hybridization or by genetic transformation.

Applicant describes a potato plant that is resistant to late blight produced by somatic hybridization between *Solanum tuberosum* and *Solanum bulbocastanum*, and teaches that said resistance is inherited on chromosome 8 from *Solanum bulbocastanum* (see pages 22-25 of the specification).

Applicant does not describe the composition or structure of the gene on chromosome 8 that confers resistance to late blight to potato, nor does Applicant describe potato plants transformed therewith. Furthermore, Applicant does not describe

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other late blight resistant potato plants produced by traditional breeding that comprise a segment of chromosome 8. In addition, at claim 3, Applicant has failed to describe RFLP markers "CT148", "CT252" and "CT68" in the instant specification. The instant specification merely refers to said RFLP markers by name on page 8, but does not describe their nucleic acid sequences.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *Fiers* 25 USPQ 2d (CAFC 1993) at 1606 that states "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself".

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

17. Claims 1 and 3-7 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the somatic hybrid potato plants produced by somatic hybridization between *Solanum tuberosum* and *Solanum bulbocastanum* as set

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forth at Table 3 on page 24 of the specification, does not reasonably provide enablement for any potato plant comprising a segment of chromosome 8 of *Solanum bulbocastanum* which comprises a gene that confers resistance to late blight or a transformed potato plant that is late blight resistant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a late blight-resistant potato plant comprising a segment of chromosome 8 of a genome from *Solanum bulbocastanum* which comprises a gene that confers said resistance to late blight, wherein said resistance gene is incorporated into the plant by somatic hybridization or by genetic transformation.

Applicant teaches a potato plant that is resistant to late blight produced by somatic hybridization between *Solanum tuberosum* and *Solanum bulbocastanum*, and teaches that said resistance is inherited on chromosome 8 from *Solanum bulbocastanum* (see pages 22-25 of the specification and Table 3 on page 24).

Applicant does not teach a gene that confers resistance to late blight to potato, nor does Applicant describe transformed potato plants.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art,

the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

At claim 7, Applicant does not teach what gene or genes from a segment of chromosome 8 of *Solanum bulbocastanum* confers late blight resistance to said plant or to the claimed potato. Applicant does not teach whether there is a single gene or a multitude of genes associated with the claimed resistance. Applicant admits that it was unclear the numbers of genes involved in the observed resistance (see page 20, 1st paragraph of the specification). Hence, Applicant invites undue trial and error experimentation, requiring one of skill in the art to empirically identify and isolate the gene or genes responsible for late blight-resistance from chromosome 8 of *Solanum bulbocastanum*.

At claims 1 and 3-6, Applicant has provided limited guidance to practice the instant invention. Thieme *et al* (1997, Euphytica 97:189-200) teach that somatic hybrids between *Solanum tuberosum* and *Solanum bulbocastanum* produce highly variable somatic hybrids that display variability in RFLP banding patterns (see page 192, right column, last paragraph). Thieme *et al* also teach that one gets a wide variation in ploidy level and a wide range of phenotypic variation (see pages 193 and 194). In addition, Thieme *et al* teach that late blight resistance is expressed at an intermediate or lower level in most somatic hybrids, possibly due to chromosomal instability and preferential elimination of some chromosomes of the wild species, somoclonal variation, and/or negative gene interactions (see page 198). Hence, the art teaches that there was unpredictability in the art at the time of Applicant's invention, especially in view of the

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statement by Thieme *et al* on page 198 "our knowledge of the inheritance of late blight resistance is insufficient". In addition, Applicant does not teach if the disclosed somatic hybrid plants are additionally resistant to potato early blight, *Erwinia* soft rot or *Verticillium* wilt as claimed in claim 5, and if not, how to obtain such plants.

Hunsperger *et al* (1996, U.S. Patent 5,523,520), teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger *et al* teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46). In particular, Hunsperger *et al* teach that a gene conferring miniature plant stature which has been identified and genetically stabilized in one cultivar of *Petunia hybrida*, a member of the Solanaceae, does not confer a miniature phenotype when introgressed into the genome of a variety of other *Petunia hybrida* cultivars (see, e.g., column 3, lines 40-41). In the instant case, the potato plant at claims 1, 3-5 and 7 encompass a non-somatic hybrid potato plant. Hence, given the limited teaching by Applicant, the unpredictability of the art at the time of Applicant's invention and the breadth of the claims, it would have required undue trial and error experimentation by one of skill in the art to isolate the gene or genes that confer resistance to late blight from chromosome 8 of the genome of *Solanum bulbocastanum*, or to identify all those potato plants having late blight-

resistance comprising a segment of chromosome 8 of the genome from *Solanum bulbocastanum* which comprises a gene that confers said resistance to late blight.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of regenerable tissue, if the potato plant does not breed true from seed, or a deposit of 2500 seed if the potato plant does breed true from seed of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public.

(a) If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a

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statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

18. Claims 1 and 6 remain rejected and claims 3 and 4 are rejected under 35 U.S.C. § 102(b) as being anticipated by Schumman *et al* (1991, *Physiologia Plantarum*, 82: A23, Abstract 134, December) taken with the evidence of Naess *et al* (2000, *Theor. Appl. Genet.* 101:697-704). This rejection has been modified from that in the previous Office Action. This rejection is repeated for the reason of record as set forth in the last Office action mailed 22 April 2002. Applicant's arguments filed 26 August 2002 have been fully considered but they are not persuasive.

Schumman discloses a somatic hybrid potato plant produced by fusion of protoplasts isolated from *Solanum tuberosum* and *Solanum bulbocastanum*.

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Schumman also discloses that the somatic hybrid potato plant has improved resistance against *P. infestans* (syn. late blight). Naess *et al* disclose that the resistance in the somatic hybrid potato plant is inherently associated with chromosome 8 of *Solanum bulbocastanum*, and is associated with RFLP maker CT88 (Applicant's SEQ ID NO: 3) (see Abstract on page 697). Hence, Schumman has previously disclosed all of the claim limitations.

Applicant argues that Schumann *et al* does not disclose a late blight-resistant potato plant that contains a resistance-conferring segment from chromosome 8 of the *S. bulbocastanum* genome (page 8 of the Remarks). This argument is not found to be persuasive because given the evidence outline supra presented by Naess *et al*, the generalized resistance to *P. infestans* as disclosed by Schumann *et al* is associated with a segment of chromosome 8 of the *S. bulbocastanum* genome, and thus is inherently disclosed by Schumann *et al*.

Conclusion

19. No claims are allowed.

20. Claims 7-9 appear to be free of the prior art because the art neither teaches nor fairly suggests "the gene" from chromosome 8 of the *S. bulbocastanum* genome that can be used to transform a potato plant to confer resistance to late blight, or a nucleotide molecule having the sequence of SEQ ID NO: 5.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
31 October 2002

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